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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,816	12/09/2003	David Burton	24,577-20US	4416

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EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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05/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/731,816

Applicant(s)

BURTON ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 1-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 55-77 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/28/04</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 55-77 in the reply filed on 27 February 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 27 February 2007.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Applicant's oath currently states "to disclose information material to the examination of this application in accordance with Title 37 Code of Federal Regulations § 1.56(a)" This statement should read "to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

Claim Objections

4. Claim 68 is objected to because of the following informalities: the claim discloses using a microphone to stimulate the patient; since a microphone is a recording device, it is not clear how it can be used to provide a stimulus. For examination purposes, the claim will be treated as though a speaker or similar device is used to provide an audible stimulus to the cochlea. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 61, 75, and 77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 61 calls for means for monitoring signal integrity, but there is no discussion of signal integrity in the specification. Claims 75 and 77 call for monitoring evoked potential response signals including latency signals or contingent potential processing signals, but the application's disclosure does not disclose monitoring any type of latency signal or contingent potential processing signal.

Claim Rejections - 35 USC § 102

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7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 55, 56, 58-60, 66-69, 71, 72, 74, and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by John (US Patent 6385486).

Regarding claims 55, 56, 58, 60, and 66, John discloses an apparatus for determining a patient's level of consciousness comprising means for acquiring at least one continuous biosignal (EEG) using at least one sensor electrode (column 5, lines 47-49), means for stimulating at least one evoked potential signal in the patient (element 16), means for acquiring at least one evoked potential signal using at least one sensor (column 6, lines 54-60), and means for calculating an index from each acquired biosignal (element 40; column 6, lines 23-25; column 9, lines 47-54; column 11, lines 5-20 and 27-29; column 12, lines 53-58) and selecting one of the indices to represent the patient's state of consciousness (column 3, lines 12-18; column 4, lines 15-17; column 8, line 55 to column 9 line 54), where the means for acquiring the biosignal and evoked potential signal utilize a common electrode sensor means (column 7, lines 4-7).

Regarding claim 59, John further discloses means for deriving the evoked potential signal from the EEG signal (element 40).

Regarding claims 67-69, John further discloses generating an evoked potential stimulus that is an auditory signal which induces a steady state response signal (element 17B; column 3, lines 38-41; column 8, lines 42-44; column 9, lines 26-28; column 12, lines 23-26).

Regarding claims 71-72, John further discloses the means for inducing an auditory evoked potential response signal including means for producing an evoked response paradigm such as a click stimulus or a response at spaced intervals within a click stimulus, where the stimulus is generated according to a predetermined sequence determined by means incorporated within the apparatus (column 6, lines 50-54; column 8, lines 42-44; column 12, lines 14-52).

Regarding claim 74, John discloses an apparatus for acquiring data in order to determine a patient's state of consciousness comprising a sensor for acquiring a continuous biosignal (column 5, lines 47-49); means for stimulating an evoked potential response signal in the patient (element 16); means for deriving at least one evoked potential response signal from the biosignal (element 40); and means for deriving an index of consciousness from the biosignal and evoked potential response signal (column 3, lines 12-18; column 4, lines 15-17; column 8 line 55 to column 9 line 54).

Regarding claim 76, John discloses an apparatus for acquiring physiological data from a patient for monitoring consciousness comprising a sensor acquiring a first continuous biosignal (column 5, lines 47-49); means for stimulating at least one evoked

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potential response signal in the biosignal (element 16); means for deriving an evoked potential response signal from the biosignal (column 6, lines 54-60); means for transforming the biosignal according to a weighting calculation according to a mediation process (column 8 line 55 to column 9 line 54); means for transforming the response signal according to the weighting calculation (column 8 line 55 to column 9 line 54); and means for calculating an index from the transformed biosignal and the transformed response signal (column 3, lines 12-18; column 4, lines 15-17; column 8, line 55 to column 9 line 54).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Loos (US Patent 5782874).

John discloses all the elements of the claimed invention, as described above, except for the biosignal being a muscular activation signal measuring eyelid movement. Loos teaches a system for monitoring a patient's state of consciousness in response to a stimulating signal that measures eyelid movement biosignals (column 11, lines 23-31, 33-36, 41-63; column 12, lines 11-13), in order to assess the patient's response to the stimulating signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John using muscular activation signals to measure eyelid movement as the biosignal, as taught by Loos, in order to assess the patient's response to applied evoked potentials.

12. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Itil (US Patent 5730146).

John discloses all the elements of the claimed invention, as described above, except for the system comprising means for monitoring the signals for signal integrity. Itil teaches a system for monitoring a patient's state using biosignals and ERPs where the signals are monitored for signal integrity (column 10, lines 13-21), in order to ensure that accurate results are obtained. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John with means for testing the integrity of the signals, as taught by Itil, in order to ensure that accurate results are obtained.

13. Claims 62 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Ennen (US Patent 6217627).

Regarding claim 62, John discloses all the elements of the claimed invention, as described above, except for monitoring the signals for signal quality. Ennen teaches a system for obtaining biosignals from a patient, where the signals are regularly monitored for signal quality (column 3 line 63 to column 4 line 2; column 4, lines 20-24 and 59-61), in order to ensure the accuracy of the signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John with means for monitoring signal quality, as taught by Ennen, in order to ensure the accuracy of the captured data.

Regarding claim 70, John discloses all the elements of the claimed invention, as described above, except for the system comprising means for displaying the functional or operational status of a sensor. Ennen teaches a system for obtaining biosignals from a patient comprising means for displaying the functional or operational status of its sensors (elements 42 and 43; column 5, lines 10-13; column 7, lines 35-49), in order to ensure that the captured data is accurate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John with means for displaying the functional or operational status of the sensor, as taught by Ennen, in order to ensure the accuracy of the captured data.

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14. Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Lahteenmaki (US Patent 6728564).

Regarding claim 63, John discloses all the elements of the claimed invention, as described above, except for the apparatus using a disposable or semi-disposable sensor. Lahteenmaki teaches a consciousness-monitoring system for measuring biosignals using disposable sensors (column 3, lines 5-7), in order to increase the system's sterility. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John with disposable sensors, as taught by Lahteenmaki, in order to ensure the system's cleanliness.

John further discloses that the system may be a portable system for monitoring consciousness where the system's sensor (element 100) includes means for activating a battery (since the battery is contained within element 100 – column 13, lines 8-13).

15. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Lahteenmaki, as applied to claims 63 and 64 above, and further in view of Semler (US Patent Application Publication 2003/0069510).

John in view of Lahteenmaki discloses all the elements of the claimed invention, as described above, except for the means for activating the energy source including the packaging of the energy source.

Semler teaches a disposable sensor system that includes an activatable energy source (battery) where the means for activation is included in the packaging (paragraph [0034]), in order to allow selective activation of the unit. It would have been obvious to

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one of ordinary skill in the art at the time the invention was made to have made the system of John in view of Lahteenmaki with means for activating the energy sources included in its packaging, as taught by Semler, in order to allow easy and selective activation of the source.

16. Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Ennen.

John discloses all the elements of the current invention, as described above, except for the system comprising means for alerting an operator to a sensor's status. Ennen teaches a system for obtaining biosignals from a patient comprising means for displaying the functional or operational status of its sensors (elements 42 and 43; column 5, lines 10-13; column 7, lines 35-49), in order to ensure that the captured data is accurate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John with means for displaying the functional or operational status of the sensor, as taught by Ennen, in order to ensure the accuracy of the captured data.

17. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Ennen, as applied to claim 73 above, and further in view of Dankwart-Eder (US Patent 6493576).

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John in view of Ennen discloses all the elements of the claimed invention, as disclosed above, except for the evoked potential signal including one of a group of latency or contingent potential processing signals.

Dankwart-Eder teaches a system for evaluating a patient's neurological state comprising obtaining evoked potential response signals such as a midlatency auditory evoked potential (MLAEP) having a duration of about 10 to 100 ms (column 5, lines 1-3) and a brainstem auditory evoked potential (BAEP) having as duration of about 2 to 20 ms (column 5, lines 18-23), in order to accurately monitor a patient's state during anesthesia. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John in view of Ennen and obtained MLAEP signals having a duration of about 10 to 100 ms and BAEP signals having a duration of about 2 to 20 ms, as taught by Dankwart-Eder, in order to accurately monitor the patient.

18. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Dankwart-Eder.

John discloses all the elements of the claimed invention, as described above, except for the evoked potential response signal including one of a group of latency or contingent potential processing signals.

Dankwart-Eder teaches a system for evaluating a patient's neurological state comprising obtaining evoked potential response signals such as a midlatency auditory evoked potential (MLAEP) having a duration of about 10 to 100 ms (column 5, lines 1-3)

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and a brainstem auditory evoked potential (BAEP) having as duration of about 2 to 20 ms (column 5, lines 18-23), in order to accurately monitor a patient's state during anesthesia. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John and obtained MLAEP signals having a duration of about 10 to 100 ms and BAEP signals having a duration of about 2 to 20 ms, as taught by Dankwart-Eder, in order to accurately monitor the patient.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 4869264 to Silberstein, which discloses a similar invention.

US Patent 6560479 to van Dronglen, which discloses a similar invention.

US Patent 6052619 to John, which discloses a similar invention.

US Patent 4201224 to John, which discloses a similar invention.

US Patent 5307818 to Segalowitz, which discloses a similar invention.

US Patent 6556861 to Prichep, which discloses a similar invention.

US Patent Application Publication 2005/0065427 to Magill, which discloses a similar invention.

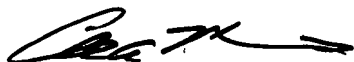
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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Ket


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